

REMARKS

Summary of the Amendment

Upon entry of the amendment, Claims 1 and 17 will have been amended. Applicant has also submitted amendments to the specification and to the drawings for clarification in response to the Examiner's objection. Therefore, Claims 1-21 currently remain pending.

Summary of the Office Action

In the Office Action, Claim 16 was rejected under 35 U.S.C. § 112 second paragraph as being indefinite. Claims 1-3, 5-8, 10-12, and 17 were rejected under 35 U.S.C. § 102(b) over the art of record. Claims 4, 9, 13, 15, 19, and 20 were rejected under 35 U.S.C. § 103(a) over the art of record. Claims 14 and 21 were merely objected to as being dependent upon a rejected base claim. Further, the Examiner objected to the Specification as failing to provide proper antecedent basis for Claim 4, and to the Drawings as not including reference number 52 labeled in Figures 3-5. By the present amendment and remarks, Applicant submits that the rejections have been overcome, and respectfully request reconsideration of the outstanding Office Action and allowance of the present application.

Acknowledgement of Allowable Subject Matter

Applicant gratefully acknowledges the Examiner's indication that Claims 14 and 21 would be allowable if rewritten to include all limitations of the base claim and any intervening claims.

Amendment to the Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter of Claim 4. Applicant has amended paragraph 32 to include the sentence: "Additionally, the flexion-extension regulating device 24 may also be formed with the upper and lower members 26, 28 being unitarily formed to each other." Applicant respectfully submits that this amendment does not contain new matter, and accordingly, requests that the Examiner indicate approval in the next Office Action.

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In response to the Office Action of March 8, 2005
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AMENDMENTS TO THE DRAWINGS

Please replace original formal Figures 3-5 with the informal Replacement Sheets for Figure 3-5.

Objection to the Drawings

The drawings are objected to as failing to comply with 37 C.F.R. § 1.84(p)(5) because Figures 3-5 do not include the reference sign “52” mentioned in the description.

Applicant has submitted informal Replacement Sheets directed to Figures 3-5 to replace original formal Figures 3-5. The Applicant’s intention is to provide Figures 3-5, which is directed to an exemplary embodiment of a knee brace discussed in paragraphs 36-39 of the specification.

As requested by the Examiner, the informal Replacement Sheets directed to Figures 3-5 now include the reference sign “52,” to accurately refer to the first motion limiting surface. Additionally, in order to more accurately refer to the second motion limiting surface 54, Applicant has added the reference sign “54” to Figures 4-5.

Accordingly, Applicant respectfully requests that the Examiner approve the aforementioned amendments to the Figures as explained above, and to indicate such approval in this next Office Action before formal drawings are submitted.

Traversal of Rejection Under 35 U.S.C. § 112 Second Paragraph

Applicant traverses the rejection of Claim 16 under 35 U.S.C. § 112 second paragraph as being indefinite. The Examiner submitted that “the claim is indefinite in that the metes and bounds cannot be determined since the claim directly or indirectly depends from claim 12 which does not further limit the claim limitations “elongated arm member is fabricated from metal” disclosed in claim 16.”

As described in the specification, paragraphs 36-39, and as shown in Figure 2, the elongated arm member 60 and the motion limiting member 48 are separate and distinct. Claim 12 recites that “the motion limiter is a flange fabricated from metal.” Claim 16, which depends from Claim 12, later recites that “the elongated arm member is fabricated from metal.”

Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claim 16 under 35 U.S.C. § 112 second paragraph as being indefinite.

Traversal of Rejection Under 35 U.S.C. § 102(b)

Applicant traverses the rejection of Claims 1-3, 5-8, 10-12, and 17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,463,751 to Bledsoe (hereinafter "BLEDSOE").

A. Review of BLEDSOE

BLEDSOE is directed to a stabilizing knee hinge that interconnects rigid femoral and tibial arms 12, 14, respectively. The hinge comprises a pair of generally circular stop limit plates 48, 50 that are rotatably mounted within two femoral joint element plates 42, 44. The hinge further includes a pair of tibial plates 66, 68 that are pivotally mounted in a spaced parallel relationship outside of the femoral plates 42, 44. The femoral plates 42, 44 are rigidly connected to the rigid femoral arm 12. The tibial plates 66, 68 are rigidly connected to the tibial arm 14. The rigid femoral and tibial arms 12, 14 may be attached to the user's leg for stabilization of the user's knee.

With particular reference to the hinge, the specification teaches that the femoral plates 42, 44 are spaced apart in a parallel relationship, and that the stop limit plates 48, 50 are rotatably mounted in between the femoral plates 42, 44. Additionally, the femoral plates 42, 44 and the stop limit plates 48, 50 are rotatably mounted utilizing a pivot 46. Furthermore, the femoral plates 42, 44 include two arcuate cam slots 58, 60. "Pivot and bearing pins 70 and 72 are mounted to arcuate cam slots 58 and 60 respectively and served to pivotally mount tibial plates 66 and 68 to femoral plates 42 and 44." See BLEDSOE, column 3, lines 55-58. As understood, it is the connection between the tibial plates 66, 68 and the femoral plates 42, 44, that BLEDSOE utilizes in order to imitate the polycentric movement of the knee.

In this regard, as understood, BLEDSOE teaches a "twin cam approach" that is intended to approximate the motion of the human knee through the use of a pivotal connection between the femoral plates 42, 44 and the tibial plates 66, 68 mentioned above. In this regard, BLEDSOE teaches that "the pivoting of the tibial arm 14 will cause pivot and bearing pins 70 and 72 to track clockwise to arcuate cam slots 58 and 60, permitting tibial

plates 66 and 68 to pivot with respect to femoral plates 42 and 44.” See BLEDSOE, column 3, lines 58-62.

BLEDSOE also apparently teaches that the pivot and bearing pins 70, 72, as shown in Figure 2, which reside in arcuate cam slots 58, 60, serve to limit the range of motion of the hinge. Specifically, the stop limit plates 48, 50 are operative to restrict the range of motion of the pivot and bearing pin 70, 72 within the arcuate cam slots 58, 60. Therefore, by limited the range of motion of the pivot and bearing pins 70, 72, the hinge limits the range of motion of a stabilized knee.

B. In re independent Claim 1 (and dependent Claims 2-16)

Applicant’s independent Claim 1 recites, *inter alia*, a motion limited member being pivotally connected to the lower member and further being pivotally connectable to the end portion of the lower strut. Applicant respectfully submits that BLEDSOE fails to disclose at least the above-noted features of the invention. Therefore, Claim 1 is patentable.

The Office Action stated that the motion limiting member of Applicant’s invention was present in BLEDSOE. In particular, the Office Action stated that BLEDSOE has “a motion limiting member (See Fig. 5 reference object 68) connectable (See Fig. 5, connectable via reference object 46) to the end portion of the lower strut (See Fig. 4 with end portion located near reference objects 40 and 38), . . .”

Applicant notes that BLEDSOE does not provide a “motion limiting member.” The BLEDSOE motion limiting member, as identified in the Office Action, is neither pivotally connected to the lower member, nor pivotally connectable to the end portion of the lower strut.

First, as shown in Figures 2-5 of BLEDSOE, the tibial plates 66, 68 are not pivotally connected to the stop limit plates 48, 50 (which were respectively identified in the Office Action as the motion limiting member and the lower member). Applicant respectfully asserts that the connection between the tibial plates 66, 68 and the stop limit plates 48, 50 is not apparently pivotal. It is not clear from the drawings or the specification of BLEDSOE that pivotal relationship is created or intended. Indeed, the only apparent pivotal connection is through the pivot 46, but this pivoting only takes place between the femoral plates 42, 44 and

the stop limit plates 48, 50. Therefore, Applicant respectfully submits that this limitation of the Applicant's Claim 1 is not present in BLEDSOE.

Additionally, Applicant respectfully asserts BLEDSOE's tibial plates 66, 68 are not pivotally connectable to the rigid tibial arm 12 (which are respectively identified in the Office Action as the motion limiting member and the lower strut). BLEDSOE apparently states that "hinge 10 is fixedly mounted to the femoral arm 12 and tibial arm 14 by means of rivets 34, 36, 38 and 40, although hinge 10 may be fastened to femoral arm 12 and tibial arm 14 by any method well known in the art such as welding." See BLEDSOE column 3, lines 19-23. Therefore, as disclosed therein, it appears that the tibial arm 14 is not pivotally connected to the tibial plates 66, 68. Indeed, as shown in Figures 2-5, the tibial plates 66, 68 are connected to the tibial arm 14 via two rivets 38, 40, which ensures that this coupling is rigid and not pivotal. Therefore, Applicant respectfully submits that BLEDSOE does not disclose a pivotal connection between a motion limiting member and a lower strut as claimed in Applicant's Claim 1.

Because BLEDSOE fails to disclose at least the above noted features of the present invention, Applicant respectfully submits that BLEDSOE fails to disclose each and every recited feature of the instant invention, and that the Examiner has failed to establish an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. § 102(b). Therefore Applicant submits that the Examiners reject of independent Claim 1 is improper and should be withdrawn.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claim 1 under 35 U.S.C. § 102(b) and indicate that this Claim is allowable over the art of record. Further, Applicant submits that Claims 2-16 are allowable at least for the reason that these Claims be depend from an allowable base claim and because these claims recite additional features that further define the present invention.

In particular, Applicant submits that BLEDSOE fails to teach, *inter alia*, the hinge system of Claim 1 wherein the knee brace is a post surgical knee brace, as is recited in Claim 2; wherein the regulating device and the motion limiting member are each fabricated from metal, as is recited in Claim 3; wherein the upper and lower members are unitarily formed to each other, as is recited in Claim 4; wherein the upper member comprises an upper body

having a generally arcuate configuration, as is recited in Claim 5; wherein the lower member comprises a lower body having a configuration sized and configured to substantially correspond with the end portion of the upper strut, as is recited in Claim 6; wherein the elongated main slot is curved, as is recited in Claim 7; wherein the upper member comprises an elongated upper slot and the lower member comprises an elongated lower slot, the upper and lower slots being substantially aligned with each other to form the elongated main slot, as is recited in Claim 8; wherein the prescribed range of motion is between about 0 to about 140 degrees, as is recited in Claim 9; wherein the motion limiting member has a motion limiting body with a first motion limiting surface, the motion limiter extending outwardly in a generally perpendicular relationship with respect to the first motion limiting surface, as is recited in Claim 10; wherein the lower member has a lower body with a second lower surface, the first motion limiting surface being connected to the second lower surface in a manner as to align the motion limiter within the elongated main slot, as is recited in Claim 11; wherein the motion limiter is a flange fabricated from metal, as is recited in Claim 12; further comprising at least one stop member removable disposed within the elongated slot for adjusting the prescribed range of motion, as is recited in Claim 13; wherein the at least one stop member is fabricated from rubber so as to be disposed within the elongated main slot through frictional fit, as is recited in Claim 14; further comprising an elongated arm member sized and configured to be disposed between the end portions of the upper and lower struts, as is recited in Claim 15; and wherein the elongated member is fabricated from metal, as is recited in Claim 16.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claims 1-13 and 15-16 under 35 U.S.C. §102(b) and indicate that Claims 1-16 are allowable over the art of record.

C. In re independent Claim 17 (and dependent Claims 18-21)

Applicant's independent Claim 17 recites, as similarly recited in independent Claim 1, inter alia, a motion limiting member engaged to the reflection-extension regulating device and being pivotally connectable to the respective end portion of the lower strut. Applicant

respectfully submits that BLEDSOE fails to disclose at least the above noted features of the invention. Therefore, Claim 17 is patentable.

Applicant respectfully submits that BLEDSOE fails to teach that the motion limiting member is *pivotally connectable to the respective end portion of the lower strut* for similar reasons as discussed *supra*. Claim 17 incorporates similar claim language as independent Claim 1, and, as discussed *supra*, Claim 1 is patentable because BLEDSOE fails to disclose each and every feature of the invention therein. Specifically, BLEDSOE fails to teach a feature common to both Claims 1 and 17, the motion limiting member being pivotally connectable to the end portion of the lower strut. For these reasons, and those detailed *supra*, Applicant submits that BLEDSOE fails to disclose each and every recited feature of the instant invention, and that the Examiner has failed to establish an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. §102(b). Therefore Applicant submits that the Examiners rejection of independent Claim 17 is improper and should be withdrawn.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claim 17 under 35 U.S.C. §102(b) and indicate that this Claim is allowable over the art of record. Further, Applicant submits that Claims 18-21 are allowable at least for the reason that these claims depend from an allowable based claim and because these claims recite additional features that further define the present invention.

In particular, Applicant submits that BLEDSOE fails to teach, *inter alia*, the knee brace as claimed in Claim 17 wherein the knee brace is a post-surgical knee brace, as is recited in Claim 18; wherein the prescribed range of motion is between about 0 to about 140 degrees, as is recited in Claim 19; wherein each of the hinge systems further comprise at least one stop member removable disposed within the elongated main slot for adjusting the prescribed range of motion, as is recited in Claim 20; and wherein each of the hinge systems further comprise an elongated arm member sized and configured to be disposed between the end portions of the respective upper and lower struts, as is recited in Claim 21.

Accordingly Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claims 17-20 under 35 U.S.C. §102(b) and §103(a) and indicate that Claims 17-21 are allowable over the art of record.

Traversal of Rejection Under 35 U.S.C. § 103(a)

Applicant traverses the rejection of Claims 4, 9, 13, 15, 19, and 20 under 35 U.S.C. § 103(a) as being unpatentable over BLEDSOE.

A. In re dependant Claim 4, 9, 13 and 15

Claims 4 and 9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over BLEDSOE. Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over BLEDSOE in view of YOUNG. Finally, Claim 15 was rejected under U.S.C. § 103(a) as being unpatentable over BLEDSOE in view of LAMB.

Applicant respectfully submits that Claims 4, 9, 13, and 15 depend from independent Claim 1 and recite additional features that further define the present invention embodied in Claim 1. Therefore, for the same reasons discussed above, BLEDSOE fails to teach or suggest at least the above-noted features of the instant invention, as recited in Claim 1. Applicant therefore submits that the teachings of BLEDSOE would not have suggested the invention as embodied in Claims 4, 9, 13, and 15 to one of ordinary skill in the art. Therefore, Applicant respectfully requests that the rejection of Claims 4, 9, 13, and 15 under 35 U.S.C. § 103(a) be withdrawn.

Further, Applicant submits that Claims 4, 9, 13, and 15 are allowable at least for the reason that they depend from an allowable base claim and because they recite additional features that further define the present invention.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claims 4, 9, 13, and 15 under 35 U.S.C. § 103(a) and indicate that these claims are allowable over the art of record.

B. In re dependant Claims 19-20

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over BLEDSOE. Claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over BLEDSOE in view of YOUNG.

Claims 19 and 20 depend from independent Claim 17 and recite additional features that further define the present invention and embodied in Claim 17. Therefore, for the same

reasons discussed above, BLEDSOE fails to teach or suggest at least the above-noted features of the instant invention as recited, in Claim 17. Applicant therefore submits that the teachings of BLEDSOE would not have suggested the invention as embodied in Claims 19 and 20 to one of ordinary skill in the art. Therefore, Applicant respectfully requests that the rejection of Claims 19 and 20 under 35 U.S.C. § 103(a) be withdrawn.

Further, Applicant submits that Claims 19 and 20 are allowable at least for the reason that they depend from an allowable base claim and because they recite additional features that further define the present invention.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claims 19 and 20 under 35 U.S.C. § 103(a) and indicate that these claims are allowable over the art of record.

Traversal of Objection to Claims 14 and 21

Applicant respectfully traverses the objection to Claims 14 and 21. The Examiner indicated that Claims 14 and 21 would be allowable if rewritten to include all limitations of the base claim and any intervening claims. Claim 14 depends from dependant Claim 13, which depends from independent Claim 1. Claim 21 depends from independent Claim 17.

Applicant reiterates and resubmits its comments regarding independent Claims 1 and 17, which are detailed *supra*. In this regard, Applicant submits that Claims 14 and 21 should be allowed because they depend from an allowable base claim. Therefore Applicant respectfully requests that the Examiner indicate that Claims 14 and 21 are allowable.

CONCLUSION

Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability and respectfully requests the Examiner to indicate allowance of each and every pending claim of the present invention.

In view of the foregoing, it is submitted that none of the references of record, when considered individually or in any proper combination thereof, anticipate or render obvious the Applicant's invention as recited in each of Claims 1-21. The applied references of record

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have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

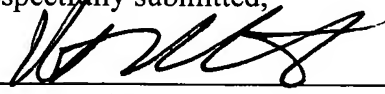
Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Date: 4/6/05 By: _____

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